DEPARTMENT OF HEALTH & HUMAN SERVICES
Administration

Public Health Service
Food and Drug

D1263 B

Refer to: CFN 1124791

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

March 18, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eugene Fife, President
Multimedia Medical Systems
400 Ray C. Hunt Drive, Suite 380
Charlottesville, Virginia 22903

Dear Mr. Fife:

During a Food and Drug Administration (FDA) inspection of your firm located in Hanover, Maryland on February 19, 20, 25, 27 and March 4, 1997, our Investigators determined that your firm manufactures the Therpac-Plus System software and distributes Compute-Rx-Plan PC3D software, which are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation, are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish a quality assurance program [21 CFR 820.20 (a)].

2. Failure to have approved, dated, and signed Device Master Records for Therpac-Plus Software and related Standard Operating Procedures (SOP) 100 through 133 [21 CFR 820.181].

3. Failure to establish written procedures for the manufacturing and processing of the finished device [21 CFR 820.160]. There is no written procedure and documentation to show that the functionality test had been performed for Therpac-Plus Software Versions V6.409106, V6.409166, V6.409266, V6.411226, V6.411196 and V6.401247, prior to release.

4. Failure to provide an adequate approval procedure for any change in the manufacturing process of a device [21 CFR 820.100 (b)(3)]. SOP 130, Change Control, does not provide an explanation for a Level 1 or Level 2 change.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Diane T. O'Brien, Acting Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201.

Sincerely yours,

Douglas I. Ellsworth

Douglas I. Ellsworth
Acting Director, Baltimore District